OPENING STATEMENT
REPRESENTATIVE STEPHEN F. LYNCH
SEPTEMBER 13, 2005 FIELD HEARING

OXYCONTIN AND BEYOND:
EXAMINING THE ROLE OF FDA AND
DEA IN REGULATING PRESCRIPTION PAINKILLERS

FIRSTLY, I WOULD LIKE TO BEGIN BY WELCOMING CHAIRMAN CANDICE MILLER TO THE 9TH CONGRESSIONAL DISTRICT HERE IN BOSTON, I THANK YOU FOR YOUR WILLINGNESS TO TRAVEL HERE TO BOSTON AND AGREEING TO HOLD THIS IMPORTANT FIELD HEARING.

THE FOCUS OF THIS HEARING HAS BEEN DESCRIBED AS "OXYCONTIN AND BEYOND: EXAMINING THE ROLE OF THE FOOD AND DRUG ADMINISTRATION (FDA) AND THE DRUG ENFORCEMENT AGENCY (DEA) IN REGULATING PRESCRIPTION PAINKILLERS."

I THINK IT IS IMPORTANT TO CLARIFY THAT THIS HEARING IS NOT JUST ABOUT ANY PARTICULAR PIECE OF LEGISLATION.

RATHER WE ARE HERE TO EXAMINE THE RECENTLY AMENDED AND ACCELERATED FDA DRUG-APPROVAL PROCESS THAT HAS SOMEHOW ALLOWED A SERIES OF DRUGS TO COME ONTO THE MARKET, MAKE THEIR WAY INTO OUR PHARMACIES, ONLY TO BE REMOVED BY THE FORCE OF LITIGATION AND GOVERNMENT PRESSURE AFTER FATALITIES AND WIDESPREAD INJURY TO INDIVIDUAL CONSUMERS.

UNFORTUNATELY, WE HAVE MANY EXAMPLES: VIOXX, THE COX-2 INHIBITOR, WITH 27,000 HEART ATTACKS AND SUDDEN CARDIAC DEATHS BEFORE IT WAS EVENTUALLY PULLED FROM THE MARKET; EPHEDRA, AN APPETITE SUPPRESSANT WITH 1,000 REPORTS OF SERIOUS HEALTH COMPLICATIONS FROM ITS USE AND AT LEAST 100 EPHEDRA-RELATED DEATHS; OXYCONTIN, PRODUCED BY PURDUE-PHARMA WITH HUNDREDS DEAD FROM OVERDOSE AND THOUSANDS HOPELESSY ADDICTED—AND THIS IS 2002 DATA; AND MOST RECENTLY PALLADONE, A POTENT NARCOTIC PAINKILLER TWICE AS POWERFUL AS OXYCONTIN AND ALSO PRODUCED BY PURDUE-PHARMA, PULLED FROM THE MARKET NINE MONTHS AFTER INITIAL FDA APPROVAL.

THESE DEVELOPMENTS IN AND OF THEMSELVES WOULD BE SERIOUS BUT IT'S IMPORTANT TO NOTE THAT IN THE CASE OF PURDUE-PHARMA A FEDERAL APPEALS COURT HAS RECENTLY RULED THAT THEIR PATENT RIGHTS ARE INVALID BECAUSE PURDUE-PHARMA

HAD LIED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE ON ITS ORIGINAL APPLICATION.

THE REVOCATION OF EXCLUSIVE PATENT RIGHTS WILL NOW ALLOW OTHER PHARMACEUTICAL COMPANIES TO PRODUCE GENERIC VERSIONS OF OXYCONTIN WHICH WILL RESULT IN WIDER AVAILABILITY AND THEREFORE GREATER POTENTIAL FOR ABUSE.

THIS ISSUE CAME TO MY ATTENTION THROUGH OUR OWN EXPERIENCE WITH OXYCONTIN. WE ARE HERE TODAY BECAUSE TOO MANY PEOPLE IN OUR COMMUNITIES AND NEIGHBORHOODS ARE STRUGGLING WITH THE PROBLEM OF PRESCRIPTION PAINKILLER ABUSE, AS WELL AS THE MISPRESCRIPTION OF THESE DRUGS, MOST NOTABLY OXYCONTIN.

ACCORDING TO A RECENT SURVEY, OXYCONTIN ABUSE WAS SECOND ONLY TO HEROIN AS THE DRUG OF ABUSE AMONG PATIENTS IN NON-METHADONE TREATMENT PROGRAMS IN BOSTON.

HOWEVER, THIS PROBLEM IS NOT JUST CONFINED TO BOSTON AND IT IS NOT JUST A PROBLEM IMPACTING THE INNER CITIES OF OUR NATION. RURAL COMMUNITIES SUCH AS MAINE, WEST VIRGINIA AND KENTUCKY AS WELL AS SUBURBAN COMMUNITIES FROM ARIZONA TO OHIO ARE ALL GRAPPLING WITH THE PROBLEM OF OXYCONTIN ABUSE AND DIVERSION. IN 2003, AN ESTIMATED 2.8 MILLION AMERICANS HAD, AT SOME POINT IN THEIR LIVES, USED OXYCONTIN FOR NON-MEDICAL PURPOSES, A SIGNIFICANT INCREASE FROM THE 1.9 MILLION IN 2002.

WE ARE ALSO VERY MUCH AWARE THAT NARCOTIC PAINKILLERS, SUCH AS OXYCONTIN, CAN BE USED SUCCESSFULLY BY CHRONIC PAIN SUFFERERS, INCLUDING CANCER PATIENTS, TO RELIEVE PAIN. IN FACT, PURDUE-PHARMA ORIGINALLY PRESENTED THE DRUG AS BEING SPECIFICALLY FOR CANCER PATIENTS AND SEVERE AND CHRONIC PAIN SUFFERERS.

I FIND IT REMARKABLE THAT THIS DRUG WAS PUT ON THE MARKET WITHOUT ANY STUDY POINTING TO ITS ADDICTIVE PROPERTIES. WHICH LEADS TO THE UNDERLYING QUESTION WE HAVE FOR FDA AND DEA—KNOWING THE POWER OF THESE DRUGS, KNOWING THE PERVASIVENESS OF MODERN MARKETING TECHNIQUES AND ALSO TAKING INTO CONSIDERATION THE ASTOUNDING PROFIT MOTIVE FOR DRUGS THAT CREATE "CUSTOMERS FOR LIFE"— HOW ADDICTIVE WILL WE ALLOW THESE DRUGS TO BECOME AND STILL BE LEGALLY MARKETED?

ALSO, THERE IS COMPOUNDING DIFFICULTY HERE IN THE FACT THAT ABSENT A SIGNIFICANT NUMBER OF DRUG-RELATED DEATHS SUCH AS WE HAVE SEEN WITH VIOXX, EPHEDRA, AND I'D ARGUE OXYCONTIN, ONCE A DRUG RECEIVES FDA APPROVAL IT IS VIRTUALLY IMPOSSIBLE TO REQUIRE FURTHER RESEARCH TO IMPROVE ITS SAFETY. THAT CONDITION LEAVES LEGISLATORS IN A POSITION WHERE THE ONLY OPTION WE HAVE IS TO RECOMMEND THE BANNING OF THAT PHARMACEUTICAL.

ADMITTEDLY, THAT IS NOT THE IDEAL SOLUTION.

HOWEVER, MUCH REMAINS UNKNOWN ABOUT THOSE "ACCIDENTAL ADDICTS" PATIENTS WHO ARE LEGITIMATELY PRESCRIBED NARCOTIC PAINKILLERS BY THEIR DOCTOR AND YET BECOME ADDICTED.

THE STORY OF OXYCONTIN, ITS APPROVAL FROM FDA, ITS MARKETING STRATEGY, AND ITS ABUSE AND DIVERSION, ALL ILLUSTRATE THE INABILITY OF THE CURRENT REGULATORY FRAMEWORK TO APPROPRIATELY ADDRESS THE PROBLEMS INHERENT IN CONTROLLED SUBSTANCES. BECAUSE THE ACTIVE INGREDIENT IN OXYCONTIN, OXYCODONE, WAS A KNOWN QUANTITY TO FDA, IT WAS NOT GIVEN ANY SPECIAL CONSIDERATION WITH REGARD TO ITS POTENTIAL FOR ABUSE AND DIVERSION DURING THE APPROVAL PROCESS. OXYCONTIN UNDERTOOK A DRUG APPROVAL PROCESS THAT EXAMINED ITS SAFETY AND EFFICACY *WHEN USED AS DIRECTED*. THEREFORE THE FDA, DEA, PHYSICIANS AND PATIENTS WERE CAUGHT UNAWARE OF THE ADDICTIVE POTENTIAL OF THIS DRUG AND ITS ATTRACTION TO THOSE WHO WOULD ABUSE IT.

I BELIEVE THAT THERE ARE SEVERAL CONCRETE WAYS IN WHICH THIS ISSUE CAN BE ADDRESSED THROUGH THE REGULATORY PROCESS AND LEGISLATIVELY IF NECESSARY. IT IS MY HOPE AND EXPECTATION THAT THROUGH THIS FIELD HEARING WE CAN EXPLORE POSSIBLE AVENUES ON THE FEDERAL LEVEL AS WELL AS LEARN WHAT OUR COUNTERPARTS ON THE STATE LEVEL ARE DOING.

WE KNOW THAT THE SIGNIFICANT GROWTH IN THE USE OF OXYCONTIN TO TREAT PATIENTS SUFFERING FROM CHRONIC PAIN HAS BEEN ACCOMPANIED BY WIDESPREAD REPORTS OF ABUSE AND DIVERSION THAT HAVE DEVASTATED INDIVIDUALS AND THEIR FAMILIES AND IN SOME CASES HAS LED TO DEATH.

HOWEVER, THE CONCERN AROUND OXYCONTIN IS ABOUT BOTH THOSE ABUSING THE DRUG AND WHO ARE BREAKING THE LAW TO GAIN ACCESS TO THE DRUG AS WELL AS THOSE INDIVIDUALS WHO WERE LEGALLY PRESCRIBED THE DRUG FOR PAIN CONTROL BUT

BECAME ADDICTED. BEFORE THE PRODUCT OXYCONTIN EVER CAME TO THE COMMERCIAL MARKET, THE MANUFACTURER PURDUE-PHARMA RECOGNIZED ITS POTENTIAL BLOCKBUSTER STATUS. HOWEVER, WHEN PURDUE-PHARMA BEGAN TO EXPAND THE MARKET FOR OXYCONTIN TO INCLUDE PATIENTS WHO SUFFERED FROM NON-CANCEROUS MODERATE TO SEVERE ACUTE AND CHRONIC PAIN FROM BROKEN BONES, DENTAL PAIN AND LOWER BACK PAIN, WE BEGAN TO SEE THE CONSEQUENCES OF PURDUE-PHARMA'S IRRESPONSIBLE MARKETING. FRANKLY, AS THIS DRUG WAS PRESCRIBED MORE AND MORE WE BEGAN TO SEE MORE AND MORE ADDICTED.

NOT ENOUGH IS KNOWN TO DATE ABOUT THE PHENOMENON OF ADDICTION THAT IS THE RESULT OF MEDICAL CARE. AND YET, AN ALARMING NUMBER OF PATIENTS MAY BE BECOMING ADDICTED, SPECIFICALLY TO PRESCRIPTION PAIN MEDICATION, AFTER LEGITIMATELY RECEIVING A PRESCRIPTION FOR SUCH TREATMENT. ACCORDING TO A 2004 SURVEY CONDUCTED BY THE OPIATE DEPENDENCY TREATMENT CENTER, THE WORLD RENOWNED WAISMANN INSTITUTE IN CALIFORNIA, 44 PERCENT OF RESPONDENTS DEPENDENT ON OXYCONTIN WERE INITIALLY PRESCRIBED THE PRODUCT BY A DOCTOR.

WE SIMPLY NEED TO BETTER UNDERSTAND THE SCIENCE OF ADDICTION TO ENSURE THAT PATIENTS AND DOCTORS HAVE ALL THE INFORMATION NECESSARY TO MOVE FORWARD WITH APPROPRIATE TREATMENT PLANS.

MOREOVER, COMPARATIVE STUDIES ARE NEEDED TO ASSESS THE RELATIVE ADDICTIVENESS, EFFICACY AND SAFETY OF AVAILABLE DRUGS. ALTHOUGH UNDOUBTEDLY MUCH GOOD CLINICAL SCIENCE IS UNDERTAKEN IN DRUG TRIALS DONE BY PHARMACEUTICAL COMPANIES, IT IS ALSO TRUE THERE ARE TOO MANY OPPORTUNITIES FOR MANIPULATION. AS A RESULT MEDICINES MAY BE COMING TO MARKET BEFORE THEY HAVE BEEN PROPERLY VETTED OR WITHOUT HAVING ENOUGH INFORMATION TO PROVIDE TO PATIENTS AND DOCTORS SPECIFICALLY ABOUT A DRUG'S POTENTIAL FOR ABUSE.

FOR INSTANCE, WE HAVE MUCH TO LEARN FROM OUR RECENT EXPERIENCE WITH PALLADONE, A POTENT NARCOTIC PAINKILLER TWICE AS POWERFUL AS OXYCONTIN. ON SEPTEMBER 24, 2004, FDA APPROVED PALLADONE, A NEW 24-HOUR EXTENDED RELEASE MORPHINE BASED MEDICATION WITH A HIGH POTENTIAL FOR ABUSE. FDA SAID IT INCORPORATED ELEMENTS FROM THE NATIONAL DRUG CONTROL STRATEGY INTO THE APPROVAL PROCESS FOR PALLADONE. FOR EXAMPLE, FDA REQUIRED THE INCLUSION OF A "BLACK BOX"

WARNING ON THE DRUG'S LABEL AND MEDICATION GUIDE. ADDITIONALLY, FDA REQUIRED THE MANUFACTURER TO IMPLEMENT A PALLADONE RISK MANAGEMENT PLAN.

HOWEVER, LESS THAN NINE MONTHS AFTER ITS INITIAL APPROVAL, ON JULY 13, 2005, PALLADONE WAS ABRUPTLY WITHDRAWN FROM THE MARKET BY THE FDA BECAUSE OF EVIDENCE THAT THE DRUG'S INTERACTION WITH EVEN MINOR AMOUNTS OF ALCOHOL IN THE PATIENT'S SYSTEM COULD LEAD TO DEATH.

IT IS ALSO NOTEWORTHY THAT PALLADONE HAD BEEN APPROVED BY FDA IN SEPTEMBER OF 2004, AND YET THE FDA STATED IT DID NOT RECEIVE ADEQUATE DATA FROM PURDUE-PHARMA UNTIL LATER WHICH ULTIMATELY LED TO THE DRUG'S WITHDRAWAL FROM THE MARKETPLACE. BECAUSE PURDUE-PHARMA IS RESPONSIBLE FOR UNDERTAKING CLINICAL TRIALS AND THEN PICKS AND CHOOSES THE DATA IT PRESENTS TO THE FDA FOR APPROVAL, PROBLEMS CAN ARISE AFTER A DRUG HAS ALREADY BEEN APPROVED AND MARKETED. MANY TIMES THE PROBLEMS ARE NOT UNCOVERED UNTIL THE DRUG IS EXPOSED TO THOUSANDS OF PATIENTS WHO REPORT ADVERSE REACTIONS. THANKFULLY, IN THE CASE OF PALLADONE, PREVIOUS DATA HIGHLIGHTED THE PROBLEM SO THAT THERE WERE NO REPORTED ADVERSE REACTIONS IN THE PATIENT POPULATION.

THE POTENTIAL FOR HARM ILLUSTRATED BY THIS CASE IS ENORMOUS. IT IS CLEAR THAT THE FDA, DEA AND THE CONGRESS NEED TO DO A BETTER JOB IN THIS AREA.

AS DESCRIBED EARLIER, OXYCONTIN ADDICTION AND ABUSE HAS SEVERELY AFFECTED MY DISTRICT AND THE PEOPLE I REPRESENT, AS WELL AS MANY COMMUNITIES NATIONWIDE. THE EXPERIENCES OF FDA AND DEA IN REGULATING OXYCONTIN AND OTHER CLASS II CONTROLLED SUBSTANCES PROVIDES US WITH A USEFUL CASE STUDY. ALTHOUGH, BOTH THE FDA AND THE DEA LEARNED MANY VALUABLE LESSONS FROM THE OXYCONTIN EXPERIENCE, IT IS CLEAR THAT THERE IS MORE THAT CAN BE ACCOMPLISHED THROUGH THE REGULATORY PROCESS. I LOOK FORWARD TO HEARING TODAY FROM DR. ROBERT J. MEYER FROM THE FDA AND JOSEPH RANNAZZISI (RAN-AS-ZEE-ZEE) FROM THE DEA ABOUT THEIR EXPERIENCES WITH OXYCONTIN AND HOW THEY ARE APPLYING THOSE LESSONS.

ADDITIONALLY, WE HAVE THE DISTINCT HONOR OF HEARING FROM TWO OUTSPOKEN LEADERS AND ENERGETIC ADVOCATES OF THE PEOPLE THEY REPRESENT IN MY FRIEND SENATOR STEVEN TOLMAN FROM WATERTOWN AND MY FRIEND AND NEIGHBOR

REPRESENTATIVE BRIAN WALLACE FROM SOUTH BOSTON. I LOOK FORWARD TO HEARING BOTH THEIR PERSPECTIVES AS STATE LEADERS ON HOW THEY'VE ADDRESSED THE ISSUE OF PRESCRIPTION PAINKILLER ABUSE—SPECIFICALLY OXYCONTIN.

ALSO, DR. JANET L. ABRAHAM, FROM THE DANA FARBER CANCER INSTITUTE IS HERE REPRESENTING THE AMERICAN CANCER SOCIETY TO EXPLAIN TO US HOW THESE POWERFUL DRUGS BENEFIT THE PATIENTS SHE SEES EVERYDAY. I KNOW DR. ABRAHAM WILL WANT TO WORK WITH US HERE ON THE COMMITTEE TO ENSURE THAT HER PATIENTS HAVE ACCESS BUT ARE ALSO PROTECTED FROM HARM.

AND, FINALLY, MY GOOD FRIEND JOHN MCGAHAN IS HERE TO TALK ABOUT THE WORK HE DOES WITH THE GAVIN FOUNDATION AND THE ADOLESCENTS AND FAMILIES HE SEES AT THE CUSHING HOUSE IN SOUTH BOSTON. THESE TWO COMMUNITY INSTITUTIONS HAVE BEEN WORKING NON-STOP TO TREAT MEN AND WOMEN, YOUNG AND OLD, WHO ARE ADDICTED TO DRUGS AND ALCOHOL. IT IS MY UNDERSTANDING THAT ALL 16 BEDS AT THE CUSHNG HOUSE ARE NOW FILLED BY ADOLESCENTS ADDICTED TO OXYCONTIN. I THINK WE WILL ALL FIND HIS TESTIMONY DISTURBING BUT ENLIGHTENING.

ONCE AGAIN, I WANT TO THANK EVERYONE FOR ATTENDING THIS HEARING TODAY. I REALLY DO BELIEVE THAT TOGETHER WE CAN COME UP WITH SOME POTENTIAL LEGISLATIVE AND REGULATORY FIXES ON THE FEDERAL LEVEL THAT WILL KEEP OUR COMMUNITIES, OUR FAMILIES, AND OUR CHILDREN SAFE.

THANK YOU AGAIN CHAIRMAN MILLER FOR RECOGNIZING THE IMPORTANCE OF THIS TOPIC AND ATTENDING TODAY'S HEARING.